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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Patent Office Board of Appeals

APPLICANT: Philip Connolly

G.A.U: 3678

SERIAL NO.: 10/045,803

EXAMINER: K. Hendricks

FILED: January 12, 2002

St. Louis, Missouri

FOR: Method of Enhancing Absorption and
Utilization of Protein

April 29, 2004

D.N.: 7287

Hon. Commissioner of Patents & Trademarks
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BRIEF FOR APPLICANT

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I. Real Parties In Interest

The parties in interest in this particular application include the inventor, Philip Connolly, and the Company to which he has assigned this application, Commercial Proteins Corporation.

II. Related Appeals and Interferences

There are no related appeals, or interference proceedings, pertaining to the subject matter of this patent application.

III. Status of Claims

The examiner issued a final rejection on October 7, 2003. Applicant filed an Amendment B, after final rejection, on or about October 30, 2003. On December 2, 2003, the examiner issued an office action stating that the Amendment B failed to place the application into condition for allowance. Thus, at that time, for purposes of appeal, the claims in the case were 1, 2, 3, 7, 8, and 10.

Applicant has previously filed a Notice of Appeal on February 5, 2004. At this time, it appears that the claims in this application include Claims 1, 2, 3, 7, 8, and 10. These are the claims upon which the Appeal Brief is filed.

IV. Status of Amendments

All of applicant's amendments subsequent to the final rejection apparently have been entered by the examiner, and therefore, the claims upon appeal are 1, 2, 3, 7, 8, and 10, as set forth in the Amendment B. These claims are set forth in the Appendix.

More specifically, applicant filed an Amendment A on July 16, 2003. That Amendment was rejected, for enablement, informalities, and obviousness on references to Meister et al. Applicant submitted the Amendment B on October 30, 2003 overcoming the informalities and attempting to render the claims more definite and non-obvious, but the examiner continued his rejections.

The Notice of Appeal was filed, and the brief was submitted accordingly.

V. Summary of the Invention

This invention uses a milk protein concentrate, or any of the other related proteins, which are fortified or cultured with a probiotic bacteria or combination of several probiotic bacteria. The milk protein concentrate which has been fortified with beneficial organisms to improve the overall digestive health of the consumer while providing the basic building blocks for muscle tissue, such as amino acids. The invention can be used to enhance absorption of protein from the gastrointestinal tract and utilization of proteins in a high protein diet. The net effect from consuming such a cultured protein seeks improved health, a higher daily degree of anabolism over catabolism, and a larger net gain in lean body tissue. In the sports nutrition area, the serious athlete or body builder should see better results in gaining muscles and will feel better in the long run. Most consumers will see increased strength, muscle development, resistance to disease.

The invention also relates to the production of a milk protein concentrate, and an improved method for manufacturing the same. The invention provides for the oral administration of a milk protein concentrate, i.e., the milk protein of skim milk that has been concentrated to a higher percentage of protein by removal of undesired constituents, such as lactose, ash, and fat. The protein concentrates are combined with probiotic bacteria including *bifido* bacterium, *acidophilus*, and yogurt culture bacteria. These bacteria are considered to be the most important intestinal bacteria for humans, and are thus classified as probiotic, which benefit living organisms.

The invention is also a method of production and administration of an improved performance milk protein concentrate that maximizes the efficient production of protein that can grow healthy muscle tissue. The invention utilizes a high quality milk protein concentrate and adds probiotic bacteria to it. The invention makes protein absorption more efficient when metabolized by the body.

VI. Issues

The issue concerned is whether or not Claims 1, 7, and 10 are definite and distinctly claim the subject matter regarding the initial protein intake of a person under 35 U.S.C. §112 2nd paragraph.

The second issue is whether or not Claims 1, 7, and 10 are really rendered so obvious and therefore unpatentable under 35 U.S.C. § 103 (a), over Bohren '465.

The third issue is whether Claims 1, 7, and 10 are really rendered so obvious and therefore unpatentable over Kronberg '524 in view of Bohren '465 under 35 U.S.C. § 103 (a).

Finally, the further issue is whether Claims 1, 7, and 10 are unpatentable over Meister '609, in view of Kronberg, and further in view of Bohren under 35 U.S.C. § 103 (a).

VII. Grouping of Claims

There appears to be three groups of claims in this appeal, one group is Claims 1, 2, and 3.

The second group is claims 7 and 8.

The third group is claim 10.

Applicant bases its appeal upon three groups of claims. These include the group as set forth above. It is applicant's position that all the claims do not stand or fall together. To the contrary, it is believed that claims 1, 2, and 3, constitute one group, claims 7 and 8 are a second group, and claim 10 is a third group. Within the groups, the claims may stand or fall together, but not all of the claims collectively.

Claims 1, 2, and 3, comprising a first group of claims, will stand or fall together.

Obviously, claims 7 and 8 are a second group, and will stand or fall together.

The third group of claims, claim 10, stands or falls alone.

VII. Argument

Claims 1, 2, 3, 7, 8, and 10:

Issue 1

The examiner rejected Claims 1, 2, 3, 7, 8, and 10, under 35 U.S.C. § 112 2nd paragraph and applicant attempted to amend independent Claims 1, 7, and 10 in order to clarify the 112 problems. The amendment B was filed after final and then the examiner stated that the amendment met the second new rejection expressed in the October 7, 2003 Office Action but failed to comply with the first new rejection expressed in same. Hence, it is believed that the claims finally rejected, of this first group, would be independent Claims 1, 7, and 10 and dependent Claims 2, 3, and 8.

Claims 1, 7, and 10 define a method of enhancing protein absorption by humans during digestion of more protein than regularly consumed. Consuming a concentrate of milk protein and probiotic bacteria, a human augments their protein eaten with meals. Claims 1, 7, 10 specify a range of total protein consumed daily including regular protein from meals and the present invention. The range as claimed provides one skilled in the art a range of total protein consumed so that the practitioner adjusts each individual's protein consumption to fall within the claimed range.

A practitioner, such as a physician, dietician, and the like, interviews an individual about their diet and meals. With diet information and food value tables, a practitioner determines the individual's starting daily protein intake. The practitioner then subtracts the starting daily protein intake from the claimed range to provide a range of actual concentrate to administer. The range of actual concentrate permits the practitioner to adjust concentrate consumption to meet the needs of the individual and still fall within the claimed range of total daily protein consumption. The training of a practitioner provides the skill in the art to interview individuals regarding diet and meals and to compute initial protein consumption using food value tables.

Issue 2

Claims 1, 7, and 10 define a method of enhancing protein absorption by humans during digestion. The enhancement arises from a concentrate of milk protein and probiotic bacteria. In one embodiment, the present invention filters liquid skim milk to a high concentration of protein and then adds probiotic bacteria to the concentrated liquid. The inoculated liquid is then spray dried. In an alternate embodiment, the present invention has a high protein milk powder mixed with a powder containing the probiotic bacteria. The inoculated concentrated powder is then mixed until homogeneous. In both embodiments, a human consumes the present invention in liquid form reaping the benefits from more efficient protein digestion encouraged by the probiotic bacteria. Two part protein concentrates appear in the '465 patent. Bohren describes a two part acidic milk powder having an acid compound coated in an edible fat with an emulsifier. This is distinct from two parts combined in a concentrate independent of their acidity or coating characteristics. Claims 1, 7, and 10 clearly describe a milk concentrate with a range of protein content and a range of probiotic bacteria concentration. To the contrary, Bohren '465 emphasizes pH and acid coating in its claimed structure.

Issue 3

Claims 1, 7, and 10 define a two part milk concentrate having a range of protein and a range of probiotic bacteria in either liquid or powder form. The range of protein makes up the major part and the probiotic bacteria make up the minor part of the concentrate. The concentrate provides protein for delivery to a human and probiotic bacteria to accelerate that delivery. A milk powder having a major part and a minor part appears in Kronberg '524. The minor part is treated by bacteria to convert sugar in skim milk thus, acidifying the minor part. The major part remains the same or has sugar added. Combined and dried, the major part and the minor part resist clumping in storage and then other bacteria upon reconstitution with water. This is distinct from powdered bacteria added to protein in a concentrate to aid absorption of protein by a human upon

reconstitution in water. Claims 1, 7, and 10 describe with clarity a two part concentrate of bacteria and protein but do not claim bacteria that inverts sugar into an acidic solution.

Issue 4

Claims 1, 7, and 10 establish either a liquid or powder concentrate of milk having ranges of protein and probiotic bacteria ingredients. For the liquid concentrate form, filtered skim milk has probiotic bacteria added. The bacteria laden skim milk is then spray dried under gentle low heat into powder form. For the powder concentrate form, powdered milk has powdered probiotic bacteria added. The two powders are then mixed mechanically to distribute the bacteria homogeneously in the concentrate. A spray dried milk powder arises in Meister '609. Meister claims a spray of food and a spray of bacteria combined and subsequently dried in at least a 100 deg C environment with mixing air to drop the temperature so some of the bacteria survive. This is distinct from powdered bacteria added to liquid or powdered milk and then spray dried or mechanically mixed respectively in a moderate temperature environment. Claims 1, 7, and 10 clearly describe combining protein and probiotic bacteria prior to drying or mixing.

It is believed that the particular method of enhancing absorption and utilization of protein of this invention, as now claimed herein, is not so suggested by the prior art, whether it be individually viewed, or in combination. While the examiner states that Meister '609 co-sprays two components to form a combined powder, it is submitted that Meister shows nothing more than two liquids, one containing bacteria, sprayed into a chamber and air dried at high temperature, no better than what is shown previously in Bohren and Kronberg, and therefore, suggests nothing with respect to a desired total daily protein consumption utilizing bacteria. Bohren simply discloses an acidic compound coated in fat solid at room temperature and Kronberg merely reveals a two part milk powder with one part being acidic and both frankly, are not believed to suggest anything in

the way Meister could be modified, to come up with the applicant's claimed invention. If suggestion is not provided by the prior art, then perhaps obviousness may also not be so apparent, in view of the case of In re Geiger, 815 F.2d 686 (Fed. Cir. 1987).

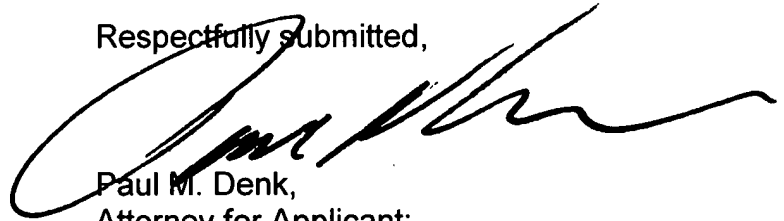
VIII. Conclusion

It is submitted that patentable subject matter is set forth in the remaining claims of this application. It is believed that the claim subject matter enables one skilled in the art to determine definitively a range of protein amount administered. It is believed that the claimed subject matter is just not rendered so obvious, to one of ordinary skilled in the art, nor is it even suggested by any combination of the prior art as cited by the examiner, notwithstanding the examiner's position. Hence, it is believed that patentable subject matter is set forth in the claims remaining in this application.

The Board's review of this matter would be appreciated.

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Respectfully submitted,

A large, stylized handwritten signature in black ink, likely belonging to Paul M. Denk, is written over the typed name and address.

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Appendix

1. A method of promoting protein absorption and utilization from the gastrointestinal tract of a subject comprising the oral administration of a combination of milk protein concentrates and probiotic bacteria in an amount sufficient to increase the subject's total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day; the milk protein concentrate having a protein content of about 65% to about 90% and there being about 100,000 to about 50,000,000 probiotic bacteria organisms per gram of milk protein concentrate.

2. The method of claim 1 wherein the probiotic bacteria is selected from the group consisting of *bifido* bacteria, *Lactobacillus plantarum*,, *Lactobacillus helveticus*, *Lactobacillus paracasei*, *Lactobacillus bulgaricus*, *Streptococcus thermophilus* and combinations thereof.

3. The method of claim 1 wherein the probiotic bacteria consists of *Bifidobacterium longum* combined with *Lactobacillus bulgaricus* and *Streptococcus thermophilus*.

7. A method of promoting protein utilization and absorption in a subject on a high protein diet comprising the oral administration of combination of milk protein concentrates and probiotic bacteria, the probiotic bacteria being selected from the group consisting of *bifido* bacteria, *Lactobacillus plantarum*, *Lactobacillus helveticus*, *Lactobacillus paracasei*, *Lactobacillus bulgaricus*, *Streptococcus thermophilus* and combinations thereof; the subject being administered an amount of the combination sufficient to increase the subject's total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day.

8. The method of claim 7 wherein the probiotic bacteria consists of *Bifidobacterium longum* combined with *Lactobacillus bulgaricus*, *Streptococcus thermophilus*, or combinations thereof.

10. A method of promoting higher ratio of anabolism as compared to catabolism, promoting muscle tissue growth, promoting amino acid production in

the intestinal tract in an athlete and promoting the utilization of protein consumed by the athlete, the method comprising the consumption by the athlete of a combination of milk protein concentrates and probiotic bacteria, the probiotic bacteria being selected from the group consisting of *bifido* bacteria, *Lactobacillus plantarum*, *Lactobacillus helveticus*, *Lactobacillus paracasei*, *Lactobacillus bulgaricus*, *Streptococcus thermophilus* and combinations thereof; the athlete consuming an amount of the combination sufficient to increase the athlete's total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day.